

REMARKS

Applicant hereby amends the claims by rewriting claims 1-3, 5, 6, 10-12, 15-17 and 23-29; cancelling claims 30 and 31, which were previously not entered; and adding new claims 32-40. All of the amended claims conform to United States Patent and Trademark Office rules and do not add new matter to the application. Applicant submits that none of these claims are either taught or suggested by the prior art. Applicant therefore requests that the Examiner renew examination of, and allow, these claims as amended, which Applicant respectfully submits are in condition for allowance as noted below.

As a preliminary matter, please note Applicant's attached:

- (1) Petition for a Three-Month Extension;
- (2) Declaration of Christopher Powers, Ph.D., PT under 37 CFR § 1.132; and
- (3) Declaration of Dean E. Cropper under 37 CFR § 1.131.

Claims 1, 15, 27, 32 and 40

Applicant submits that all of independent claims 1, 15, 27 and newly added independent claims 32 and 40 are in condition for allowance. Support for a "concentrated inward tracking member" that provides "concentrated inward pressure" (claims 1-29); and a "concentrated pressure strap" that provides "concentrated inward pressure" (new claims 32-40) is found, *e.g.*, in Figs. 1 and 2b. Support for "wherein a first opposing portion of the concentrated inward pressure strap is operatively attached to the lateral hinge and a second opposing portion of the concentrated pressure strap is operatively attached to the medial hinge, the concentrated pressure strap being aligned substantially perpendicular to the longitudinal axes" (new claim 39), can be found, *e.g.*, in Figs. 1 and 3.

Neither Labour nor Lehman anticipates the claims because they:

- (1) do not necessarily teach at least one of the structural limitations recited within claims 1, 15, or 27 (or added claims 32 or 40), and indeed**
- (2) cannot perform these limitations' recited functions.**

Labour

Claims 15-16, 19-21, and 26 stand rejected as being anticipated by United States patent number 4,445,505 ("Labour").

In view of the attached Declaration of Christopher Powers, Ph.D., PT, Applicant respectfully submits, however, that the Examiner allow the claims as amended for the following reasons:

Labour does not explicitly teach the following limitations of these claims:

"a concentrated inward tracking member that fits operatively over, and provides concentrated inward pressure against, the patella;

wherein the concentrated inward tracking member provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove."

Labour does not inherently teach the structural limitation, "concentrated inward tracking member", or its recited function, *i.e.*, in which it "provides concentrated inward pressure" because these features are not *necessarily* present in Labour, as declared by noted expert, Dr. Christopher Powers. "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. 'The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)." *Manuel of Patent Examining Procedure* § 2112, IV, Eight Ed., August 2001, Latest Rev., August 2006 ("M.P.E.P.") (*emphasis added*). Indeed, based on Labour's teachings as viewed by Dr. Powers himself, Labour "only possibly contains a concentrated inward tracking strap or member for a patella". Powers' Decl., para. 7. Dr. Powers also states that someone having lesser skill than himself (*e.g.*, someone having only ordinary skill in the art) would definitely not have viewed Labour as having a concentrated inward tracking member. *Id.*

Thus, Labour's strap 80 would not be recognized by one having ordinary skill in the art as being a "concentrated inward tracking member[.]". First, no matter how tightly Labour's device is adjusted, the patella is nested and thus protected from concentrated inward pressure by the opening 30, *see* Labour, col. 3, lines 3-4 ("relieves pressure against the patella"). Besides, it appears that

Labour's strap 80 can be tightened only to a very limited extent. The lengths of hook and loop fabric disclosed in Labour may be too short ever to overlap such that strap 80 would provide concentrated inward tracking to a patella. Second, strap 80 is likely too wide to provide concentrated inward pressure. It overlaps the top side of opening 30, which nestles the patella within. Third, the fabric used at the time of Labour is too thick for strap 80 to provide concentrated inward tracking of the patella. The neoprene fabric most likely used as the elasticized fabric in Labour's brace is too thick for strap 80 to concentrate inward pressure onto a patella through opening 30. Therefore, because one having ordinary skill in the art would definitely not recognize Labour's device as having a concentrated inward tracking member, Labour does not possess the structural limitation of a concentrated inward tracking member for purposes of an inherency argument.

Moreover, because the device as disclosed in Labour does not have a concentrated inward tracking member, and could not have one without the device being redesigned, Labour cannot be read as inherently disclosing a concentrated inward tracking member. *See M.P.E.P. § 2112, IV* ("The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).").

Labour also "fails to show that the natural result of its devices' operations... would be application of concentrated inward pressure onto the patella." Powers' Decl., para. 7. Referring again to the context of strap 80, it appears that pads 54 and 38 create a nest that coincides with opening 30, in which the patella is protected from concentrated inward pressure. *See Labour*, col. 3, lines 35-37 ("It will be noted that the vertical medial edge 54 of pad 36 is curved and lies closely adjacent the edge 32 of the opening 30.") As a result, opening 30 of Labour creates a raised perimeter around the patella over which strap 80 partially lays over, but does not inwardly impinge upon, the patella. Thus, mere prevention of anterior displacement by the strap in Labour cannot inherently rise to the level of meeting the requirement of concentrated inward pressure (even though these straps are elastic and adjustable), because the circumferential force of a tightened strap compresses only the raised portions that lie around the perimeter of the patella, and not the patella.

To the contrary, relatively less pressure on the patella in the presence of increased circumferential pressure about the remaining entire circumference of the leg at the knee joint, or increased pressure on the pads, which provide support about the sides of the patella, compresses the joint so as to force the patella out and away from the trochlear groove. Evidence of this adverse effect is found by the stated function of strap 80, which is passively to "prevent anterior dislocation", not to provide concentrated inward force to an already misaligned patella. As a result, increased

tightening of the adjustable strap 80 would likely have the opposite effect of concentrated inward pressure so that such action would in effect tend to push the patella outwardly and away from the trochlear groove. *See, i.e.*, Labour, col. 1, line 8 to col. 2, lines 1-2 (“The strap is stretchable and intended to tighten the sleeve about the knee and thereby force the pads [not the patella] firmly in position”); Labour, col. 4, lines 25-48 (“the user may pull the strap as tightly as desired to effectively reduce brace diameter and apply pressure on the pads [not the patella] 36 and 38... ...the strap applies pressure to the pad... to provide a barrier to prevent lateral displacement... ...the strap covers a portion of opening 30 [and] when the strap is pulled tight across the front of the sleeve [no mention of pressure on patella] the strap [passively] prevents anterior displacement of the patella [out] through the opening.”).

Thus, Labour does not inherently teach a concentrated inward tracking member, because it would not be recognized as necessarily present to one having ordinary skill in the art. “Inherency... may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, at *id*.

The stated purpose of Labour further illustrates this point. With respect to the patella, Labour is meant only to “include means for preventing lateral displacement of the patella”; it does not have a concentrated inward tracking member or provide concentrated inward tracking. Labour, col. 1, lines 27-29; *see also*, col. 1, line 7-8. Thus, Labour merely prevents lateral displacement and perhaps thereby maintains patella positioning – it does not have a concentrated inward tracking member.

As such, Applicant respectfully submits that a *prima facie* case of anticipation does not exist with regard to Labour.

Lehman

Claims 1-8, 14-21, and 26-29 stand rejected as being anticipated by United States patent number 3,804,084 (“Lehman”).

In view of the attached Declaration of Christopher Powers, Ph.D., PT, Applicant respectfully submits, however, that the Examiner allow the claims as amended for the following reasons:

Lehman does not explicitly teach the following limitations of these claims:

“a concentrated inward tracking member that fits operatively over, and provides concentrated inward pressure against, the patella;

wherein the concentrated inward tracking member provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.”

Lehman does not inherently teach the structural limitation, “concentrated inward tracking member”, or its recited function, *i.e.*, in which it “provides a concentrated inward pressure” because these features are not *necessarily* present in Lehman, as declared by noted expert, Dr. Christopher Powers. “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily* present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. ‘The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)” M.P.E.P. § 2112, IV (*emphasis added*). Indeed, based on Lehman’s teachings as viewed by Dr. Powers himself, Lehman “only probably contains a concentrated inward tracking strap or member for a patella”. Powers’ Decl., para. 8. Dr. Powers also states that someone having lesser skill than himself (*e.g.*, someone having only ordinary skill in the art) would probably not have viewed Lehman as having a concentrated inward tracking member. *Id.*

Thus, Lehman’s strip 90 would not be recognized by one having ordinary skill in the art as being a “concentrated inward tracking member[.]” First, no matter how tightly Lehman’s device is adjusted, the patella is nested and thus protected from concentrated inward tracking by the opening 36. Besides, Lehman’s strip 90 can be tightened only to a limited extent. The lengths of hook and loop fabric disclosed in Lehman are too short ever to overlap such that strip 90 would provide concentrated inward tracking of a patella. Second, strip 90 is too wide to provide concentrated inward pressure. It overlaps the top and bottom sides of opening 36, which nestles the patella within. Third, Lehman’s fabric is too thick for strip 90 to provide concentrated inward tracking. The “relatively thick” “1/8 to 3/8 inch” fabric used around the patella in Lehman’s brace is too thick for strip 90 concentrate inward tracking onto a patella through opening 36. *See, e.g.*, col. 3, line 30; col.4, lines 36-37; and col. 5, line 7. Therefore, because nothing in Lehman’s device can provide concentrated inward tracking with any degree of certainty, it does not possess the structural limitation of a concentrated inward tracking member.

Moreover, because the device as disclosed in Lehman does not have a concentrated inward tracking member, and could not have one without the device being redesigned, Lehman cannot be read as inherently disclosing a concentrated inward tracking member. *See* M.P.E.P. § 2112, IV (“The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).”).

Lehman also “fails to show that the natural result of it devices’ operations... would be application of concentrated inward pressure onto the patella.” Powers’ Decl., para. 7. Referring again to the context of strip 90, whatever “elastic superimposed support which is adjustable”, *see Lehman*, col. 2, lines 19-20, that is provided by the overlock strip in Lehman – is provided only to tie the stays one to another, not to provide concentrated inward tracking. Stay 50 on the lateral side of the patella and stay 52 on the medial side of the patella - along with strips 60 and 62, which overlay “relatively thick” felt edges 20 and 22 on the top and bottom sides of the patella, respectively - provide a superimposed stack of “relatively thick” layers under strip 90. These superimposed layers create a protective nest around the patella that roughly coincides with opening 36, which is formed *also* by layered cut outs 30 and 32. These layers that form opening 36 collectively protect the patella from concentrated inward tracking. As a result, opening 36 of Lehman creates a raised perimeter around the patella over which strip 90 lays, but does not inwardly impinge upon the patella. Thus, any support from the strip in Lehman cannot rise to the level of meeting the requirement of concentrated inward pressure, because the circumferential force of a tightened strap compresses only the raised portions that lie around the perimeter of the patella, and not the patella.

To the contrary, relatively less pressure on the patella in the presence of increased circumferential pressure about the remaining entire circumference of the leg at the knee joint, or increased pressure on the stays against the sides of the patella, which provide support about the circular perimeter of the patella – compresses the joint so as to force the patella out and away from the trochlear groove. Evidence of this adverse effect is found by the stated function of strip 90, which is passively to provide “elastic superimposed support”, not to provide concentrated inward tracking force to a patella. As a result, increased tightening of the adjustable strip 90 would have the opposite effect of concentrated inward pressure so that such action would in effect tend to push the patella outwardly and away from the trochlear groove. *See Lehman Fig. 4*, wherein strip 90 compresses raised upper and lower strips 60 and 62 and raised stay means 50 and 52, and thereby squeezes the area surrounding the patella. This pressure thus causes outward forces on the knee cap, which makes a resulting concentrated inward force improbable.

Thus, Lehman does not inherently teach a “concentrated inward tracking member” that “provides concentrated inward pressure” because it would not be recognized as necessarily present to one having ordinary skill in the art. “Inherency... may not be established by probabilities or possibilities. “The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’ ” *In re Robertson*, at *id*.

As such, Applicant respectfully submits that a *prima facie* case of anticipation does not exist with regard to Lehman.

Labour does not inherently teach the limitations missing from Cawley

Cawley in view of Labour

Claims 1-14, 17-18, and 22-25, and 27-29 stand rejected as being obvious over United States patent number 6,551,264 (“Cawley”) in view of Labour.

In view of the above-recited reasoning, however, Applicant respectfully submits that all of these claims are in condition for allowance. In short, Labour does not teach, either inherently or explicitly, a concentrated inward tracking member, which is a structural element in claims 1, 15, and 27. Moreover, the art is replete with evidence that teaches away from the use of a concentrated inward tracking member. Nearly every, if not every, knee brace in the prior art - in some way, shape, or form - teaches a protective nest or opening about the wearer’s patella similar to the ones found in Labour and Lehman.

New claims 32-40

Applicant requests that the Examiner enter newly added claims 32-40, which Applicant respectfully submits are also in condition for allowance. None of Labour, Lehman, nor any of the prior art teach or suggest a “concentrated inward pressure strap” that provides “concentrated inward pressure” to a patella, as is recited in both claims 32 and 40.

Date of Applicant’s actual reduction to practice

Applicant also refers the Examiner to the attached Declaration of Dean E. Cropper under 37 CFR § 1.131, in which Applicant hereby shows actual reduction to practice, prior to March 29, 2002, of subject matter covered by all of independent claims 1, 15, 27, 32 and 40.

For all of the forgoing reasons, Applicant respectfully requests that the examiner reexamine and allow all of claims 1-29 and 32-40.

Respectfully submitted,

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Ronald C. Harris, Jr. (Reg. No. 48,901)
The Harris Firm
922 N Street, NW, Ste. 101
Washington, DC 20001
(703) 786-7661